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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,825	09/12/2003	Thomas Herbert Peterson	134687NV (MHM 15085US01)	7037
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EXAMINER MEHTA, PARIKHA SOLANKI				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/660,825

Applicant(s)

PETERSON, THOMAS HERBERT

Examiner

PARIKHA S. MEHTA

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-SB-08)
Paper No(s)/Mail Date ____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION**Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

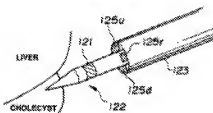
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kami et al (US Patent No. 5,339,799), hereinafter Kami ('799).

Regarding claims 1, 4 and 6, Kami ('799) discloses a medical instrument comprising a support member 123 operatively connected to a needle-tipped laser probe 122 ("a flexible engaging member having an operative distal tip", wherein "flexible" is interpreted as meaning "capable of being bent") and a strain gauge 121 affixed to an outer portion of the needle, wherein the strain gauge is capable of detecting movement of the operative distal tip of the laser probe (Fig. 18, col. 12 line 62 – col. 13 line 5, col. 13 lines 24-28, col. 28 lines 39-67, col. 29 lines 1-14). As Applicant has not limited the structure of the inventive strain gauge as being specifically modified away from known gauges in order to achieve the function of "detect[ing] movement of the operative distal tip of the laser probe", and, as a skilled artisan would readily recognize, the gauge of Kami ('799) is capable of achieving the function set forth in the claim, Kami ('799) sufficiently meets that which is claimed. Furthermore, the laser probe of Kami ('799) is interpreted to constitute a needle by the common definition of that term as set forth by Merriam Webster ("a slender pointed object resembling a needle"). And as Kami ('799) distinctly states that the strain gauge detects pressure "when the laser probe is **placed on a tissue**") emphasis added, this further supports the position that the reference gauge is provided to detect active placement/movement of the probe relative to the tissue.

FIG. 18



Source: Kami ('799); Drawings p. 11 of 35

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 3, 5 and 7-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kami ('799).

Regarding claims 2, 3, 8 and 9, Kami ('799) substantially teaches all features of the present invention as previously discussed for claims 1 and 4, but does not expressly teach the strain gauge to change resistance upon deflection, nor does Kami ('799) expressly teach the strain gauge to be within an electrical circuit as claimed. Examiner hereby takes Official Notice that it is known in the art to use a Wheatstone bridge (i.e., an "electrical circuit in which a potential difference occurs when the resistance of the strain gauge changes") with a strain gauge to detect deflection of medical instruments. Accordingly, it would have been obvious to one of ordinary skill in the art to use a known Wheatstone bridge with the strain gauge of Kami ('799) in order to achieve the present invention, as such a combination of known prior art elements to yield predictable results has previously been held as unpatentable (see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claim 5, Kami ('799) does not expressly teach a second strain gauge affixed to the laser probe. Applicant does not disclose that the additional strain gauge solves a particular problem, is used for a specific purpose, or presents a patentable advantage over prior art single-gauge arrangements. Furthermore, it has previously been held that the mere duplication of known elements is unpatentable over the prior art (see *MPEP* 2144, *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)). Accordingly, it would have been obvious to one of ordinary skill in the art to include a second strain gauge on the laser probe of Kami ('799) in order to achieve the presently claimed invention.

Regarding claims 7, 12 and 13, Kami ('799) teaches all features as discussed for claims 1 and 4, and further teaches an optical system that is capable of tracking the position of the laser probe (col. 19 lines 8-37, Fig. 38). Although Kami ('799) does not expressly teach the optical system for specifically

tracking the laser probe, Kami ('799) does generally teach the optical system as being useful for performing surgery under precise observation. As such, a skilled artisan would find it obvious to use the optical system of Kami ('799) to track the laser probe, also of Kami ('799), during a surgical procedure in view of the teachings of Kami ('799).

Regarding claim 10, Kami ('799) includes a processing unit 128 that correlates the output of the strain gauge with an amount of movement of the laser probe (col. 13 lines 8-17).

Regarding claim 11, Kami ('799) includes an embodiment having a display that shows the medical instrument (Figs. 35 & 36).

Regarding claims 14-20, Kami ('799) teaches a method of using the system discussed for claims 1-13 including steps of tracking a medical instrument with an optical tracking system (col. 19 lines 8-37), and a second method of affixing a strain gauge to an outer portion of the probe (col. 12 line 62 – col. 13 line 5, “a strain gauge [detects pressure] when the laser probe is placed on tissue”, col. 13 lines 24-28; see also the discussion of this limitation as it pertains to claim 1 above). Although Kami ('799) does not explicitly teach the use of these two methods together in a single procedure, it would have been obvious to one of ordinary skill in the art to do so in view of the teachings of Kami ('799) that the optical system is advantageous for realizing precise operations (col. 19 lines 11-12).

Regarding claims 21 and 22, the strain gauge of Kami ('799) provides information regarding a location of the deflectable operative distal tip in relation to a longitudinal axis of the support member as previously discussed for claim 1.

Regarding claim 23, Kami ('799) teaches that the deflection of the strain gauge indicates that the probe is in contact with tissue (col. 13 lines 1-6), which constitutes the provision of information regarding a location of the operative distal tip as claimed.

Response to BPAI Decision

5. In the decision of 5 Nov 2010, the Examiner's rejection of claims 1-23 was reversed. The Board's reversal was based on the position that the Examiner failed to adequately show inherency of the non-disclosed features in the prior art; specifically, the Board takes the position that detection of movement of the distal tip of the probe cannot reasonably be shown to be an inherent feature of Kami (BPAI decision p. 7). Examiner clarifies that the rejection is not based on inherency, but rather the notion that the reference apparatus is structurally equal to that which is claimed, and it is capable of performing the claimed functions; and thereby the reference fairly meets the claim. It is well established that, while

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features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); see also MPEP 2114). Also pertinent is the precedent holding that “a claim covers only what a device is, not what it does” (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)).

Furthermore, it has also previously been held that a recitation with respect to the manner in which the claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art if the prior art provides all structural limitations of the claim (*Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)). When comparing the fact pattern of *Marsham* to the invention at hand, the precedent limitation of the mixing means being completely submerged correlates directly to the present limitation of the gauge detecting movement. In both cases, although the function was directly recited (i.e., not merely established as being “for” achieving the function, but with language that actively recites the function itself), it is clear that the prior art structure is the same as that which is claimed in the application, and therefore a rejection based on anticipation is proper.

As the method claims were rejected under 35 U.S.C. 103(a), not 35 U.S.C. 102 (b), any discussion of whether the reference inherently possesses non-disclosed features is irrelevant to the propriety of the rejection.

For at least the foregoing reasons, the claims remain rejected over the prior art of record as detailed herein.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8:00 am - 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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